

PATENT COOPERATION TREATY

NDT
2 31/8/04
01/06/2004
2

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
BOULT WADE TENNANT
Attn. Thomson, Neil David
Verulam Gardens
70 Gray's Inn Road
London WC1X 8BT
UNITED KINGDOM

RECEIVED

31 AUG 2004

**BOULT WADE
TENNANT**

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year) **30/08/2004**

Applicant's or agent's file reference

P61329W000

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.

PCT/GB2004/002315

International filing date
(day/month/year)

01/06/2004

Applicant

BESPAK PLC

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.


The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority

 European Patent Office, P.B. 5818 Patentaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Vera Eberhardt

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P61329WO00	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/GB2004/002315	International filing date (day/month/year) 01/06/2004	(Earliest) Priority Date (day/month/year) 16/10/2003
Applicant BESPAK PLC		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB2004/002315

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A dispenser (1) comprising a housing (3), a pressure sensor (22), processing means (23) and a display means (27), the housing being shaped for receiving, in use, a dispensing container (5) of the type containing medicament and having valve means for dispensing the medicament in metered volume doses, wherein, in use, the pressure sensor is capable of detecting a pressure signature produced on dispensation of medicament from the dispensing container, wherein the pressure sensor is operatively connected to the processing means for relaying signals indicative of the pressure signature for processing by the processing means, the processing means being programmed to analyse said signals and compare said signals against one or more data sets containing data indicative of one or more control pressure signatures, the processing means being programmed to use a result of said comparison to detect the quantity of medicament dispensed compared to an intended volume of the metered dose volume.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2004/002315

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 390 088 B1 (NOEHL KLAUS ET AL) 21 May 2002 (2002-05-21) column 1, line 56 -column 3, line 21 column 4, line 47 -column 5, line 10 column 5, line 62 -column 7, line 37 figures ---	1-32
X	WO 95/07723 A (MEDTRAC TECH INC) 23 March 1995 (1995-03-23) the whole document ---	1-32
A	WO 02/058771 A (BACON RAYMOND J) 1 August 2002 (2002-08-01) page 4, line 20 -page 6, line 2 figures 1,2 --- -/--	1-32

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *8* document member of the same patent family

Date of the actual completion of the international search

18 August 2004

Date of mailing of the international search report

30/08/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Azaïzia, M

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB2004/002315

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 138 669 A (ROSSITER DANIEL J ET AL) 31 October 2000 (2000-10-31) column 4, line 46 -column 5, line 37 column 6, line 20 -column 7, line 25 column 7, line 62 -column 8, line 10 figures 1-4 ---	1-32
A	US 2003/052196 A1 (FUCHS KARL-HEINZ) 20 March 2003 (2003-03-20) the whole document ---	1-32
A	US 2003/075171 A1 (JONES ANTHONY PATRICK ET AL) 24 April 2003 (2003-04-24) page 1, paragraph 12 page 2, paragraphs 23-28 page 2, paragraph 36 -page 3, paragraph 45 figures ---	1-32
A	WO 00/12162 A (BONNEY STANLEY GEORGE ;JONES ANTHONY PATRICK (GB); GLAXO GROUP LTD) 9 March 2000 (2000-03-09) page 6, line 10-12 page 7, line 25 -page 10, line 13 figures 1-5 -----	1-32

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB2004/002315

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6390088	B1	21-05-2002	DE 4422710 C1 AT 192659 T AU 701504 B2 AU 2886795 A BR 9508137 A CA 2193858 A1 DE 59508328 D1 DK 767683 T3 WO 9600595 A1 EP 0767683 A1 ES 2145281 T3 GR 3034098 T3 HK 1012296 A1 JP 10501999 T PT 767683 T US 6119684 A ZA 9505303 A US 5587606 A	14-09-1995 15-05-2000 28-01-1999 25-01-1996 04-11-1997 11-01-1996 15-06-2000 09-10-2000 11-01-1996 16-04-1997 01-07-2000 30-11-2000 02-02-2001 24-02-1998 31-08-2000 19-09-2000 14-02-1996 24-12-1996
WO 9507723	A	23-03-1995	WO 9507723 A1	23-03-1995
WO 02058771	A	01-08-2002	EP 1357965 A1 WO 02058771 A1 US 2004069301 A1	05-11-2003 01-08-2002 15-04-2004
US 6138669	A	31-10-2000	US 5676129 A AU 2068897 A WO 9733640 A1	14-10-1997 01-10-1997 18-09-1997
US 2003052196	A1	20-03-2003	DE 10146815 A1 EP 1293224 A2 JP 2003111844 A	22-05-2003 19-03-2003 15-04-2003
US 2003075171	A1	24-04-2003	AU 5031601 A WO 0160438 A2 EP 1255580 A2 JP 2003522610 T	27-08-2001 23-08-2001 13-11-2002 29-07-2003
WO 0012162	A	09-03-2000	AU 5970899 A WO 0012162 A1 EP 1107810 A1 JP 2002523190 T US 6651651 B1	21-03-2000 09-03-2000 20-06-2001 30-07-2002 25-11-2003

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/002315

International filing date (day/month/year)
01.06.2004

Priority date (day/month/year)
16.10.2003

International Patent Classification (IPC) or both national classification and IPC
A61M15/00

Applicant
BESPAK PLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Azaïzia, M

Telephone No. +49 89 2399-6960



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

10/575866

International application No.
PCT/GB2004/002315

AP20 Rec'd PCT/PTO 17 APR 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/002315

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	10-14, 17, 18, 22-29
	No: Claims	1-9, 15, 16, 19, 20, 21, 30-32
Inventive step (IS)	Yes: Claims	
	No: Claims	10-14, 17, 18, 22-29
Industrial applicability (IA)	Yes: Claims	1-32
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)

PCT/GB04/02315

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

1. Reference is made to the following documents:
D1: US-B1-6 390 088 (NOEHL KLAUS ET AL) 21 May 2002 (2002-05-21)
D2: WO-A-95/07723 (MEDTRAC TECH INC) 23 March 1995 (1995-03-23)
2. Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. In fact, the embodiments of the invention described on page 5 ("... **flow sensor** ..." - cf. lines 26-28) do not fall within the scope of the independent claim 1 ("A dispenser comprising ... a **pressure sensor** ..."). This inconsistency between the independent claim 1 and the description leads to doubt concerning the matter for which protection is sought, thereby rendering the claim unclear (Article 6 PCT).
- 2.1 For the purpose of the present written opinion and since it is clear from the description that flow sensors are also intended for use in a dispenser according to the present invention, the expression "a pressure sensor" used in the claims has been interpreted as directed to any kind of sensor having a proportional output signal.
3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
- 3.1 The document **D1** discloses (the references in parentheses applying to this document) a dispenser ("inhaler 1" shown in fig. 1) comprising:
 - a housing ("housing" - cf. c.5, l.64), a **sensor** ("first thermal sensor 5"), processing means ("electronic modul 3") and a display means ("optical display unit 34"), the housing being shaped for receiving, in use, a dispensing container ("supply container 2") of the type containing medicament and having valve means for dispensing the medicament in metered volume doses, wherein, in use
 - **the sensor** ("first thermal sensor 5") is capable of detecting a **signature** ("temperature profile" - cf. c.3, l.4) produced in dispensation of medicament from the dispensing container (cf. c.1, l.64 to c.2, l.4), wherein **the sensor** ("first thermal sensor 5") is operatively connected to the processing means ("electronic modul 3")

for relaying signals indicative of **the signature** for processing by the processing means (cf. c.1, l.56 to l.63),

- the processing means ("electronic modul 3") being programmed to analyse said signals and compare said signals against one or more data sets containing data indicative of one or more **control signatures**, the processing means being programmed to use the result of said comparison to detect the quantity of medicament dispensed compared to an intended volume of the metered dose volume (cf. c.2, l.40 to l.58).

- 3.2 The document **D2** discloses (the references in parentheses applying to this document) a dispenser ("electronic inhalant device 100" shown in fig.1) comprising:
- a housing ("body housing 120"), **a sensor** ("main sensing element 425" - cf. p.15, l.36 to p.16, l.12 - fig. 4), processing means ("electronic assembly 400" shown in fig. 4) and a display means ("LCD 1135" shown in fig.11), the housing being shaped for receiving, in use, a dispensing container ("canister package 215" shown in fig.2) of the type containing medicament and having valve means for dispensing the medicament in metered volume doses, wherein, in use
 - **the sensor** ("main sensing element 425") is capable of detecting **a signature** produced in dispensation of medicament from the dispensing container (cf. p.15, l.36 to p.16, l.12), wherein **the sensor** is operatively connected to the processing means ("electronic assembly 400") for relaying signals indicative of **the signature** for processing by the processing means (cf. p.16, l.25 to p.17, l.7 - fig.8),
 - the processing means ("electronic assembly 400") being programmed to analyse said signals and compare said signals against one or more data sets containing data indicative of one or more **control signatures**, the processing means being programmed to use the result of said comparison to **implicitly** detect the quantity of medicament dispensed compared to an intended volume of the metered dose volume (cf. p.18, l.8 to p.19, l.1 - fig.8).

The subject-matter of independent claim 1 is therefore not new (Article 33(2) PCT).

4. The additional features of dependent claims 2-32 are **EITHER** already known from D1 and/or D2, **OR** define slight constructional changes in the dispenser which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently,

dependent claims 2-32 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT) and/or inventive step (Article 33(3) PCT).

5. The subject-matter of claims 1-32 is considered industrially applicable since it can be made or used in any kind of industry (Article 33(4) PCT).

Re Item VII

Certain defects in the international application (form and content)

6. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.
7. The independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, with those features known in combination from the prior art (documents D1 and/or D2) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
8. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).